

REMARKS

A. Status of the Claims

Claims 1-31 have been canceled without prejudice to future prosecution. Claims 32-40 are currently pending.

Claim 32 has been amended to recite "wherein said biologically active agent and said delivery-enhancing transporter form a non-covalently bound complex." Support for this amendment may be found throughout the specification as filed, for example, at page 23, lines 9-12 (stating, "[d]erivatized biological agents can then be combined with a suitable delivery-enhancing transporter **to form a non-covalently bound complex** which is suitable to delivery of the biological agent in vivo," (emphasis added)); Figure 2; Examples 1-3; and at page 10 lines 15-21, stating,

[i]n one group of embodiments, the present invention provides a composition of a delivery-enhancing transporter and a biologically active agent. The composition is a **non-covalent** combination of the delivery-enhancing transporter and the biologically active agent. Rather than a covalent composition, the components are held in an ionic association, typically viewed as an ion pair. Despite the term "ion pair," the invention will, in some embodiments, include compositions of one or more biologically active agents in association with one delivery-enhancing transporter [emphasis added].

Therefore, no new matter is added with entry of this amendment.

B. Rejection Under 35 U.S.C. §102(b)

The Examiner has maintained the rejection of claims 32 and 40 under 35 U.S.C. §102(b) as allegedly anticipated by Sumner-Smith *et al.* (Canadian Patent App. 2,094,658). The Examiner asserts that the claims as written are not limited to compositions having a distinct, unconjugated delivery-enhancing transporter.

In order to expedite prosecution, Applicants have amended claim 32 to recite "wherein said biologically active agent and said delivery-enhancing transporter form a non-covalently bound complex." Because the claims as amended explicitly recite that the delivery-

enhancing transporter is non-covalently bound to the biologically active reagent, Applicants respectfully submit that the Examiner's rejection is now moot. Therefore, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. §102(b).

D. Rejection Under 35 U.S.C. §103(a)

The Examiner has maintained the rejection of claims 32, 33 and 40 under 35 U.S.C. §103(a) as allegedly obvious in view of Katz *et al.* (United States Patent No. 6,005,004). The Examiner asserts that the claims are rejected on the same basis as set forth in the rejection under 35 U.S.C. §102(b) (*i.e.* the claims as written are not limited to compositions having a distinct, unconjugated delivery-enhancing transporter).

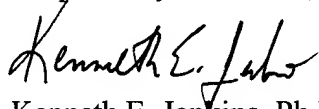
For the reasons cited above in the discussion of the rejection under 35 U.S.C. §102(b) (*i.e.* amended claim 32 recites "wherein said biologically active agent and said delivery-enhancing transporter form a non-covalently bound complex"), Applicants respectfully submit that the Examiner's rejection under 35 U.S.C. §103(a) is now moot. Therefore, Applicants respectfully request withdrawal of the rejection.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,



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Attachments

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